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The comparison between pulmonary rehabilitation with music therapy vs pulmonary rehabilitation alone in patients hospitalized because of asthma exacerbation

Submission date
08/01/2017

Recruitment status
No longer recruiting

Registration date
18/01/2017

Overall study status
Completed

Last Edited
17/06/2019

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Asthma is a common long-term condition where the airways can become narrowed due to inflammation (swelling). Some of the symptoms are cough, wheezing and breathlessness. Studies on the quality of life in asthma patients have shown that symptoms depend not only on the severity and length of the disease, but also on the social and mental condition of the patient and their family. Strong emotions can be responsible for the worsening of asthma symptoms and therefore mental disorders like depression and stress can affect the patient's treatment. Previous research shows the development of treatments accompanied by relaxation methods, including music therapy, can help improve mental wellbeing and physical symptoms in people with asthma. However, it can be difficult to measure how well these programs work. This study is looking at changes in cortisol (a hormone that is released when the body is under stress) levels after patients have taken part in a relaxing activity (music therapy). The aim of this study is to find out whether music therapy can help improve the physical symptoms and mental wellbeing of people suffering from asthma.

Who can participate?
Adult patients who are in hospital and have asthma.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive standard treatment. This involves working with a physiotherapist to help learn breathing techniques and how to clear their airways. Those in the second group receive standard treatment as well as music therapy. This involves listening to 30 minutes of relaxing music, prepared by music therapists, to help improve mental wellbeing once a day throughout their hospital stay. Treatment for all participants takes place until they are discharged from hospital (this may vary depending on the patient). From the start of the study until they are discharged from hospital, participants have their breathing assessed by the clinical team and the amount of oxygen in their blood measured using a finger probe. At the start of the study and then after the

program has finished, participants provide blood samples which are tested for stress hormone levels and undergo assessments to see how well they are controlling their asthma.

What are the possible benefits and risks of participating?
Participants may benefit from receiving extra treatments and more in-depth monitoring of their condition. There are no major risks involved in participating but some participants may experience discomfort or bruising from blood tests.

Where is the study run from?
Jagiellonian University Medical College (Poland)

When is the study starting and how long is it expected to run for?
June 2016 to December 2019

Who is funding the study?
Jagiellonian University Medical College (Poland)

Who is the main contact?
Dr Agnieszka Sliwka

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
K/ZDS/006156

Study information

Scientific Title
The comparison between pulmonary rehabilitation with music therapy vs pulmonary rehabilitation alone on respiratory drive, cortisol level and asthma control in patients hospitalized with asthma exacerbation

Study objectives
Music therapy as a complementary treatment with pulmonary rehabilitaion has a positive effect on respiratory drive, psychological state and asthma control in patients with asthma exacerbation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics Committee of the Jagiellonian University, 28/04/2016, ref: 122.6120.75.2016

Study design
Double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet (Polish only)

Health condition(s) or problem(s) studied
Asthma

Interventions
Patients will be randomly assigned to two groups. Randomization will be done by one researcher using a computer program available at: www.randomizer.org. When new patient will be recruited a phone information about randomization's result will be given by the researcher.

Experimental Group:
Participants will achieve a standard pharmacological treatment together with respiratory physiotherapy and passive music therapy (30 minutes of relaxing music prepared by music therapists, emitted from mp3 via a headphones). Applied program of treatment and pulmonary rehabilitation will be carried out according to guidelines of GINA report and the American Association of Cardiovascular and Pulmonary Rehabilitation.
Physiotherapy and music therapy will be delivered once daily during the hospitalization period.

Physiotherapy will be adopted to the patient's condition and might include: airways clearance techniques, reeducation of breathing pattern, diaphragmatic breathing and techniques to reduce shortness of breath.
Music therapy methodology is based on data available in the literature. The music repertoire was prepared on the base of results of the previous study examining music preferences of 80 patients with asthma.

Control Group:
The treatment program will be exactly the same with the exception of music therapy. Instead, music controls will be listening to radio broadcasts about popular-science and nature.

In both groups the intervention takes place daily for the duration of their hospital stay.

Participants in both groups are followed up before, during and after intervention. Before treatment the following are measured: respiratory drive, blood cortisol level, dyspnoe, asthma control using Asthma Control Test, Asthma Quality of Life Questionnaire, and Brief Music in Mood Regulation Scale. After treatment the respiratory drive, blood cortisol level, dyspnoe, asthma control are measured. During the participants entire hospital stay they will have their dyspnoe, mood and blood saturation level measured.

Intervention Type
Behavioural

Primary outcome measure
1. Respiratory drive will be measured using Spirometer Master Lab at baseline and post-intervention
2. Blood cortisol level will be measured by testing blood samples taken early in the morning at baseline and post-intervention
3. Dyspnoea will be measured using Modified 0–10 category-ratio Borg scale and Fifteen-Count Breathlessness Score daily until discharged; saturation will be measured using portable finger spirometer daily until discharge

Secondary outcome measures
1. Asthma control will be measured using the Asthma Control Test at baseline and Asthma Quality of Life Questionnaire at baseline and post-intervention
2. General emotion regulation and musical engagement will be measured using the Brief Music in Mood Regulation Scale at baseline

Overall study start date
01/06/2016

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Hospitalized patients with asthma
2. Aged 18 years and over
3. Provision of informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Total final enrolment
65

Key exclusion criteria
1. Contraindications to pulmonary rehabilitation
2. Severe phase of coronary heart disease
3. Severe pulmonary hypertension
4. Significant hepatic dysfunction
5. Severe cognitive impairment
6. Advanced cancer
7. Damage of auditory system
8. Other comorbidities

Date of first enrolment
01/10/2016

Date of final enrolment
31/05/2019

Locations

Countries of recruitment
Poland

Study participating centre
Jagiellonian University Medical College
Department of Rehabilitation in Internal Diseases
Skawinska 8
Krakow
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31-066

Sponsor information

Organisation
Jagiellonian University Medical College

Sponsor details
Świętej Anny 12
Kraków
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Sponsor type
University/education

ROR
https://ror.org/03bqmcz70

Funder(s)

Funder type
University/education

Funder Name
Jagiellonian University Medical College

Results and Publications

Publication and dissemination plan
A publication is planned in peer reviewed, indexed journal from area of allergology, asthma or complementary therapies at the end of 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Magdalena Pieniazek (pieniazek.m@interia.pl)

IPD sharing plan summary
Available on request